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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/506,703

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Michael S. Kopreski

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06/19/2008

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EXAMINER

NATARAJAN, MEERA

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

06/19/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/506,703

**Applicant(s)**

KOPRESKI, MICHAEL S.

**Examiner**

MEERA NATARAJAN

**Art Unit**

1643

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 16, 17, 21, 22, 24, 26 and 28-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-15, 18-20, 23, 25, and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Applicant's amendments in the reply filed on 03/31/2008 is acknowledged and entered into the record.
2. Accordingly Claims 1-36 are pending, Claims 1-9, 16-17, 21-22, 24, 26, 28-36 have been withdrawn as being drawn to non-elected inventions/species.
3. Claims 10-15, 18-20, 23, 25, and 27 will be examined on the merits.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 10-15, 18-19, 23, 25, and 27 are rejected under 35 U.S.C. 102(a) as being anticipated by Hasselmann et al. (Clinical Chemistry, Vol. 47, No. 8, pp.1488-1489, August 2001).
6. The Claims are drawn to method of detecting extracellular RNA from an apoptotic body in serum from a patient, the method comprising extracting, separating, isolating or purifying the apoptotic body from serum, labeling RNA in the apoptotic body or cDNA derived therefrom or its amplified product using a labeled primer or probe specific to RNA or cDNA derived therefrom and detecting the labeled RNA or cDNA from the apoptotic bodies using fluorescent labeled probes and flow cytometry and

wherein the presence of the RNA of the apoptotic bodies in the serum is associated with a cancer or a premalignant condition.

7. Hasselmann et al. teach the detection of extracellular tyrosinase mRNA within apoptotic bodies from peripheral blood of melanoma patients. Hasselmann et al. teach three methods of isolating mRNA from apoptotic bodies, which include synthesizing and amplifying cDNA using PCR, and labeling RNA and detecting it with fluorescence microscopy to identify typical granular structures representing apoptotic bodies that contained RNA or gel electrophoresis (see Fig. 1). Hasselmann et al. disclose "it was demonstrated that DNA and RNA are packaged separately into apoptotic bodies, producing two types of apoptotic bodies, one type containing RNA and no DNA and the other type containing DNA and no RNA. This finding suggests that extracellular mRNA may circulate within apoptotic bodies, which may decrease their susceptibility to nucleases" (see p. 1488, left column, lines 20-27). Hasselmann et al. also disclose that tumor-derived mRNA associated with apoptotic bodies remains stable in serum, indicating that RNA within apoptotic bodies is protected from degradation in serum even after prolonged exposure to nucleases and tumor-specific RNA has been also found recently in serum and plasma samples from cancer patients.

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claim 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hasselmann et al. (Clinical Chemistry, Vol. 47, No. 8, pp.1488-1489, August 2001) in view of Mok et al. (J. Natl. Cancer Inst. Vol. 93(9), pp.1458-1464 Oct. 2001).

11. The Claims are drawn to the method of Claim 10 wherein the RNA is extracted from the apoptotic body and hybridized to a solid substrate such as a bioelectric interface.

12. The teachings of Hasselmann et al. are presented in the 102(a) rejection set forth above. Hasselmann et al. does not teach hybridizing the extracted RNA to a bioelectric interface. This deficiency is made up for in Mok et al.

13. Mok et al. teach identification of potential serum markers in ovarian cancer using microarray technology. RNA was isolated and pooled from three ovarian cancer cell lines and from three normal human ovarian surface epithelial cells lines.

Complementary DNA generated from these pools was hybridized to a microarray slide and genes overexpressed in the cancer cells were identified (see Abstract).

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14. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to use the technique taught by Mok et al. to identify RNA of apoptotic bodies in serum/plasma samples. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Hasselmann et al. and Mok et al. because the microarray technology would allow a potential screening method to detect increased levels of RNA from apoptotic bodies in plasma samples with a high throughput.

**All other rejections are withdrawn in view of Applicant's amendments to the claims.**

### ***Conclusion***

15. Claims 10-15, 18-20, 23, 25, and 27 are rejected.
16. No Claim is allowed.
17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEERA NATARAJAN whose telephone number is (571)270-3058. The examiner can normally be reached on Monday-Thursday, 9:30AM-7:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN

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/Larry R. Helms/

Supervisory Patent Examiner, Art Unit 1643